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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,747	04/13/2001	Hal Sternberg	BIOT008	4271

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BOZICEVIC, FIELD & FRANCIS LLP
200 MIDDLEFIELD RD
SUITE 200
MENLO PARK, CA 94025

EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/834,747

Applicant(s)

STERNBERG, HAL

Examiner

Frank I Choi

Art Unit

1616

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 March 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE: Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☒ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

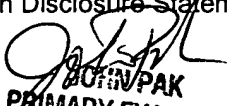
Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____


PRIMARY EXAMINER
GROUP 1200



Continuation of 2. NOTE: Applicant now proposes to exclude sodium bicarbonate as a pharmacological means for reducing the CO₂ level of a subject in an amount sufficient to reduce the risk of acidosis/acidemia which amendment was not made previously and was specifically required in at least the method claims. As such, said amendment appears to raise new issues which would require further consideration and/or search. Also, said amendment appears to raise the issue of new matter as the Specification does not indicate that sodium bicarbonate may be excluded from the pharmacological means .

Continuation of 5. does NOT place the application in condition for allowance because: the proposed amendments have not been entered. However, should they be entered the following applies: The proposed amendment would overcome the 35 USC 112, 2nd paragraph rejection of claims 14 and 18, would overcome the rejection of claims 1-25 over Taylor (US 5,514,536) based on Applicant's arguments relative to the exclusion of conventional biological buffers as specifically defined by Applicant's specification but not as to Applicant's arguments relative to refuting inherency. With respect to the rejection of claims 1-25 over Segall et al. ('880 or '801), Examiner has duly considered Applicant's arguments but deems them unpersuasive for the reasons set forth in the prior Office Actions and the further reasons below. Applicant's exclusion of sodium bicarbonate is directed to pharmacological means for reducing CO₂ level in an amount sufficient to reduce the risk of acidosis/acidemia, however, the prior art does not indicate that the sodium bicarbonate is used to reduce CO₂ levels and Applicant does not appear to have offered any evidence which shows that sodium bicarbonate reduces CO₂ levels. As such, the negative limitation does not appear to include exclusion of the use of sodium bicarbonate as disclosed in the prior art. Applicant's arguments relative to oxygenators does not appear to be supported by probative evidence (See In re Schulze, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 43 USPQ2d 1362 (Fed. Cir. 1997) (attorney arguments do not constitute evidence)). The fact remains that the prior art oxygenator appears to be the same device described by Applicant to be suitable for the claimed method. When the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. In re King, 231 USPQ 136 (Fed. Cir. 1986) Further, the expressly disclosed methods also involve the use of anesthetics which are specifically recited as pharmacological means of reducing the CO₂ level. Applicant does not appear to have shown that the expressly disclosed methods do not inherently reduce CO₂ levels sufficient to reduce the risk of acidosis/acidemia. Applicant's claims indicate that the risk of acidosis/acidemia is reduced, as such, acidosis/acidemia may still occur. As such, the fact that the prior art teaches that sodium bicarbonate may optionally be used to manage acidosis does not appear to overcome inherency rejection. Finally, Applicant appears to exclude oxygenators from the definition of pharmacological means. However pharmacological means is defined to include any means in which a pharmacological agent is employed to achieve the desired reduction of CO₂ level. Oxygen is clearly a pharmacological agent, as such, the use of oxygenators does not appear to be excluded by the limitation "pharmacological means" .